K071254

510(k) SUMMARY

SMALL INTESTINAL VIDEOSCOPE SYSTEM

MAR 25 2008

1. General Information

- Applicant

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No.: 8010047

- Official Correspondent:

Laura Storms-Tyler
Executive Director
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610
Phone: 484-896-5688
FAX: 484-896-7128
Email:Laura.storms-tyler@olympus.com
Establishment Registration No.: 2429304

- Manufacturer
  Small intestinal videoscope:

Aizu Olympus Co., Ltd.
500 Aza Muranishi Ooaza,
Niidera, Monden-machi,
Aizuwakamatsu-shi, Fukushima, Japan, 965-8502
Establishment Registration No.: 9610595

Splinting tube:

OLYMPUS MEDICAL SYSTEMS CORP. Hinode Plant
34-3 Hirai Hinode-machi, Nishitama-gun,
Tokyo, Japan 190-0182
Establishment Registration No.: 3003637092

Balloon control unit:

Shirakawa Olympus Co., Ltd.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No.: 3002808148

2. Device Identification

- Trade Name: SMALL INTESTINAL VIDEOSCOPE SYSTEM
- Common Name: Small Intestinal Videoscope
- Regulation Number: 21CFR 876.1500 / 876.5980
- Regulation Name: Endoscope and accessories / Gastrointestinal tube and accessories

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- Regulatory Class: II
- Product Code: FDA, KNT & NWB

3. Predicate Device Information

Model	510(k) #	Manufacturer	Class	Product Code
Small Intestinal Videoscope System	K051551	Olympus Medical Systems Corp.	II	FDA & KNT

4. Device Description

The subject device, Small Intestinal Videoscope system, is designed for endoscopy and endoscopic surgery within the small intestine. This system is composed of Small Intestinal Videoscope, Single Use Splinting Tube, and Balloon Control Unit and its accessories. The subject system is compatible with NBI observation which utilizes narrow-band spectrum to enhance contrast of the surface structure and fine capillary patterns of the mucous membranes. Also, the subject system utilizes a balloon attached to the splinting tube to facilitate advancement of the endoscope well within the small intestine.

5. Indications for Use

SMALL INTESTINAL VIDEOSCOPE SYSTEM

This system is composed of the small intestinal videoscope and the other ancillary equipment. The small intestinal scope has been designed to be used with an Olympus video system center, light source, balloon control unit, splinting tube, documentation equipment, video monitor, electrosurgical unit, endo-therapy accessories such as biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the upper and lower digestive tract including the esophagus, stomach, duodenum, small intestine and colon, by either oral or anal insertion.

Indications for Use of the components are as follows:

SIF-Q180 (SMALL INTESTINAL VIDEOSCOPE)

This instrument has been designed to be used with an Olympus video system center, light source, single use splinting tube, balloon control unit, documentation equipment, video monitor, endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the upper and lower digestive tract (including the esophagus, stomach, duodenum, colon, and small intestine) by either oral and anal insertion.

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OBCU (BALLOON CONTROL UNIT)

This balloon control unit has been designed for inflating and deflating the balloon attached to the distal end of a single use splinting tube in order to assist the insertion of an Olympus –designated small intestinal endoscope.

6. Comparison of Technological Characteristics

The subject system is basically identical to the predicate double-balloon system in intended use, and similar in specifications except for eliminating the balloon attached to the distal end of the small intestinal videoscope and addition of NBI function. The NBI observation function is identical to that of the EVIS EXERA 160A System which has been 510(k) cleared under K051645 for the use within the gastrointestinal tract.

7. Conclusion

When compared to the predicate devices, the SMALL INTESTINAL VIDEOSCOPE SYSTEM does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Olympus Medical Systems Corporation
% Ms. Laura Storms-Tyler
Vice President
Regulatory Affairs & Quality Assurance
Olympus America, Incorporated
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

MAR 25 2008

Re: K071254
Trade/Device Name: Small Intestinal Videoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDA, FED, NWB and OCS
Dated: February 21, 2008
Received: February 22, 2008

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K071254

Device Name: **SMALL INTESTINAL VIDEOSCOPE SYSTEM**

Indications For Use:

SMALL INTESTINAL VIDEOSCOPE SYSTEM

This system is composed of the small intestinal videoscope and the other ancillary equipment. The small intestinal scope has been designed to be used with an Olympus video system center, light source, balloon control unit, splinting tube, documentation equipment, video monitor, electrosurgical unit, endo-therapy accessories such as biopsy forceps and other ancillary equipment for endoscopic diagnosis and endoscopic surgery within the upper and lower digestive tract including the esophagus, stomach, duodenum, small intestine and colon, by either oral anal insertion.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071254

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Indications for Use

510(k) Number (if known): K071254

Device Name: **SMALL INTESTINAL VIDEOSCOPE SYSTEM**

Indications For Use:

Indications for Use of the Components are as follows:

SIF-Q180 SMALL INTESTINAL VIDEOSCOPE

This instrument has been designed to be used with an Olympus video system center, light source, single use splinting tube, balloon control unit, documentation equipment, video monitor, endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the upper and lower digestive tract (including the esophagus, stomach, duodenum colon, and small intestine) by either oral and anal insertion.

OBCU Balloon Control Unit

This balloon control unit has been designed for inflating and deflating the balloon attached to the distal end of a single use splinting tube in order to assist the insertion of an Olympus-designated small intestinal endoscope.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K071254